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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,201	03/05/2002	Yacoob Tabani	220005	6365

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08/05/2003

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EXAMINER

CHAUDHRY, SAEED T

ART UNIT

PAPER NUMBER

1746

12

DATE MAILED: 08/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
10/091,201	TABANI ET AL.	
Examiner	Art Unit	
Saeed T Chaudhry	1746	

-- Th MAILING DATE of this communication app ars on the cover sheet with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-93 is/are pending in the application.
- 4a) Of the above claim(s) 25-34 and 77-93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 6, 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicant's preliminary amendments and remarks filed June 24, 2003 have been acknowledged by the examiner and entered. Claims 1-24 have been canceled and claims 25-93 are pending in this application for consideration.

Applicant's election with traverse of Group II, claims 35-76 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that while the Group 1, 2, and 4 claims are independent, in the sense that they include independent rather than dependent claims, they have a cleaning mechanism in common in that the mechanism of cleaning involves the generation of two phase flow of a cleaning liquid and a gas. Thus applicant submit these claims can be and should be considered together as Group I. This is not found persuasive because Group I, claims 25-34 require to remove contaminants from a hollow tubing with two phase flow and do not require backflushing hollow fiber or with a solution having pH 7; wherein Group III, claims 35-76 requires backflushing hollow fibers with solution from dialysate side and gas from lumen side and does not require two phase or solution of pH 7 and wherein Group III requires cleaning with a solution having a pH 7 and does not requires two phase flow or backflushing from dialysate side with solution and gas from lumen side. Group IV, claims 88-93 is an apparatus, wherein the apparatus as claimed herein can be used to practice another and materially different process such as mixing liquid in the tank or introducing air in the liquid for increasing air concentration in the liquid or the process as claimed can be practice another and materially different apparatus such as tank without an inlet for a liquid sterilant.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

Claims 45, 46, 48, 53, 62-63, 68 and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 45, 62 and are confusing and indefinite because it is not clear how the two phase flow is reverse? Is gas flow is reversed or cleaning solution is reversed to reverse the two phase flow?

Claim 46 recites the limitation "air" in line 2. There is insufficient antecedent basis for this limitation in the claim. The applicant is advised to change this to - - gas - -.

Claim 48, 63, are confusing and indefinite because it is not clear what is meant by a cleaning liquid alone. Is the cleaning solution Is also passed through the lumen side or only through the dialysate side?

Claim 53 recites the limitation "the dialyzer" in last line. There is insufficient antecedent basis for this limitation in the claim. The applicant is advised to change this to - - hemodialyzer-

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Claims 62-63 has insufficient antecedent basis for "two-phase flow".

Claims 68 and 70 are duplicate claims. The applicant is advised to cancel one claim.

Double Patenting

Claims 35-37, 40-41, 44-53, 56, 58-59, 61-66, 68, 70-71 and 73-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 9, 12-17, 20, 22, 25, 28, 33, 35, 38, of U.S. Patent No. 6,454,871 in view of Kopp et al (EP-289532) and Labib et al (6,027,572).

Labib et al (6,454,871) disclose a method of cleaning hemodialyzer by forming a mixture of liquid droplets dispersed in a gas along a surface of a passageway from a mixture of gas and liquid. The passageway either shell side or tube side of a shell and tube geometry. The mixed-phase flow is formed by adding the liquid into the preambule surface of the passageway wherein the gas is flowing. The direction of the mixed flow is reversed one or more times. The passageway is rinsed after removal of debris. The liquid includes oxidizing agent or biocides. The passageway comprises an input header, a plurality of conduits, and wherein the mixed-phase flow contacts the inside of the conduits and the inside of the input header and the output header. The liquid include a surfactant (see claims). The reference fails to disclose backflushing, or disclose specifically that cleaning solution is injected from a dialysate side of the dialyzer or passing gas into lumen side of the dialyzer.

Kopp et al (EP-289532) disclose a method of cleaning retained solids in porous hollow fibers within a tubular shell or housing by introducing a pressurized gas into the fiber lumens while liquid is flowing through the shell or housing. The pressurized gas being at a pressure sufficient to cause the gas to pass through the walls of the fibers against the pressure then prevailing on the shell side with liquid flowing. Then, while maintaining pressurized gas flow into the fiber lumens, either increasing the shell side or housing or decreasing the shell side pressure below the normal gaseous cleaning pressure by stopping inflow of liquid to the shell and thereafter returning to the normal gaseous cleaning pressure by resuming flow of liquid through the shell in a reverse direction. The shell is drained before commencement of backwash (see claims).

Labib et al (6,027,572) disclose method for removing biofilm and debris from tubing by mixing aqueous solution and surfactant with a gas under pressure so as to form a turbulent mixture and passing through the tubing. The aqueous solution may contain oxidizing agent and solution may be heated up to 50 degree Centigrade. the oxidizing agents include aqueous hydrogen peroxide or peroxy compound such as perborates, periodates and peroxycarboxylic acids (col. 4, lines 5-8 and 55-56). The gas under pressure can be pulsed to increase the scrubbing action (col. 5, lines 15-16). The tubing is rinsed with water after cleaning (see claim 8).

It would have been obvious at the time applicant invented the claimed process to incorporate the cited process of cleaning hollow fibers within a tubular shell as disclosed by Kopp et al in the process of Labib et al. This is because Kopp et al system of hollow fibers in a shell is equivalent to a dialyzer as disclosed by Labib et al and Kopp et al disclose that backwashing increases the flux. Therefore, one of ordinary skill in the art would expect that backwashing would clean the hollow fibers of the dialyzer. Forming two phase flow mixture of droplets and air would be inherently formed in the process of Kopp et al since liquid is applied through the shell side and air is provided through the lumen side. Furthermore, one of ordinary skill in the art would use the teaching of Patent 6,027,572 to manipulate the temperature of the solution and pulsate the air for pulsating action of the air to increase the scrubbing action of the solution and air. One of ordinary skill in the art would include surfactant and oxidizing agent such as hypochlorite because 572' disclose that peroxide may increase the time period that elapses before biofilm starts to re-form.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy

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reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Van Ornam, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and © may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 35-40, 42-53, 55, 57-67, 69, 71-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopp et al in view of Kross.

Kopp et al (EP-289532) were discussed supra. However, the reference fails to disclose to remove contaminants from a hemodialyzer or a dialyzer and using chelating agent or sodium hydroxide or surfactant or oxidizing agent such as hypochlorite

Kross (5,628,959) disclose a method and apparatus for sterilizing hemodialysis. The dialysis machine which contains the dialyzer is represented in FIG. 1. More specifically, FIG. 1 illustrates the location of hollow-fiber dialyzer 1, blood flow from the patient 2, blood flow to the patient 3, dialysate solution flow into the dialyzer 4, dialysate solution flow out of the dialyzer 5 and pump 6 which controls blood flow through the dialyzer. Dialysate solution (about 500 ml/minute) is moved into and out of the dialyzer by a series of pumps, one of which extracts a specified amount of spent dialysis fluid from the circuit and replaces it with fresh dialysate (see col. 1, lines 46-56). In general, the present invention is directed to compositions and methods for sterilizing dialyzers for reuse by a dialysis patient. An aqueous solution was prepared containing 3.03% sodium chlorite and 1.37% tetrasodium EDTA. One part of this solution was combined with eleven parts of an aqueous solution containing 0.38% lactic acid, 1.68% sodium hydroxide, and 0.04% sodium benzoate. The resulting mixed solution had a pH of 4.0, and was introduced into the blood-tubing side (7) of a previously-used dialyzer, from which it passed directly to the dialysate side (9), as part of a reprocessing operation, after the dialyzer tubing had been flushed with water to eliminate soluble and suspended blood products (see col. 10, lines 55 to ol. 11 line 5). After disinfecting a hemodialyzer as in Example 2, the sterilant is removed by first draining the dialysate side of the hemodialyzer free of sterilant and then flushing a buffered dialysate through the dialysate side of the dialyzer in a sufficient quantity so as to osmotically neutralize the acidity of the sterilant in the blood side of the tubing. Thereafter a pyrogen-free physiological saline solution is flushed through the blood tubing to completely displace the residual components of the neutralized sterilant. While continuing the flow of buffered dialysate (see col. 12 lines 5-15).

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It would have been obvious at the time applicant invented the claimed process to incorporate the chelating agent, sodium hydroxide, and oxidizing agent as disclosed by Kross into the process of Kopp et al for the purpose of disinfecting the dialyzer and to provide high antimicrobial activity against microorganisms which can contaminate dialyzers. The solution having a pH range from 6.0 to 8.0 (see claim 4). One of ordinary skill in the art would utilize the process of Kopp et al for removing contaminants from the dialyzer because Kopp et al disclose to remove contaminants from an apparatus having porous hollow fibers. Since dialyzers have porous hollow fibers. Therefore, one would expect to have same results to remove contaminants from a dialyzer which have hollow fibers too. The claimed process uses 20 to 60 degrees Centigrade temperature for the cleaning solution. Since Kross disclose to remove contaminants from the dialyzer at room temperature. Therefore, one of ordinary skill in the art would manipulate the temperature of the cleaning solution since higher temperature would increase the kinetic energy of the solution for the removal of the contaminants.

Claims 41, 56, 68 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopp et al in view of Kross as applied to claim 35-40, 42-53, 55, 57-67, 69, 71-76 above, and further in view of Kawaguchi et al .

Kopp et al and Kross were discussed supra. However, the reference fails to disclose to include a surfactant in the cleaning solution.

Kawaguchi et al (5,658,466) disclose a method of sterilizing and cleaning dialyzing membranes with aqueous solution of surfactant.

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It would have been obvious at the time applicant invented the claimed process to incorporate a surfactant as disclose by Kawaguchi et al in the process of Kopp et al to enhance the cleaning efficiency since surfactant would increase the wetability of the cleaning solution.

Claims 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kopp et al in view of Kross as applied to claim 35-40, 42-53, 55, 57-67, 69, 71-76 above, and further in view of Lee et al.

Kopp et al and Kross were discussed supra. However, the reference fails to disclose to include heparin.

Lee et al (4,622,140) disclose that heparin is an anticoagulant in blood processes.

It would have been obvious at the time applicant invented the claimed process to incorporate heparin as disclose by Lee et al in the process of Kopp et al for the purpose of hindering the blood clot.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saeed T. Chaudhry whose telephone number is (703) 308-3319. The examiner can normally be reached on Monday-Friday from 9:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gulakowski Randy, can be reached on (703)-308-4333. The fax phone number for this Group is (703)-305-7719.

When filing a FAX in Gp 1700, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communication with the PTO that are for entry into the file of the application. This will expedite processing of your papers.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

*Saeed T. Chaudhry
July 28, 2003*


**FRANKIE L. STINSON
PRIMARY EXAMINER
GROUP 3400-1700**